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**VIA OVERNIGHT DELIVERY AND ELECTRONIC MAIL**

April 3, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Comments on Notice of Proposed Rulemaking  
Registration of Food Facilities  
Federal Register notice February 3, 2003  
Docket No.02N-0276

Dear Sirs/Madams:

On behalf of Federal Express Corporation ("FedEx"), these comments are submitted in response to a Notice of Proposed Rulemaking published in the Federal Register on February 3, 2003, regarding proposed regulations for the registration of food facilities in accordance with the BioTerrorism Preparedness and Response Act of 2002. While FedEx supports the intent of the act and FDA's efforts to create implementing regulations, we believe there are certain critical revisions and clarifications required in the proposal.

**Section 1.226: Exemptions**

The intent of the proposed regulations, and the Act itself, is to require registration for those facilities engaged in actual manufacturing or processing activities, and storage or warehousing of such food articles. Transportation services provided by carrier, whether air or surface, do not qualify as manufacturing, processing, or storage, and neither do they meet any of the definitions proposed in section 1.227. Therefore, we propose that an additional subsection be added to the exemptions proposed in 1.226 as follows:

1.226(h): Air, ocean, or surface transportation companies providing transportation and related services for import to the United States. "Holding" or "manufacturing/processing" activities as defined in part 1.227 would require registration.

**Section 1.227: Definitions**

§ 1.227 contains definitions for several critical terms in this proposal, including "facility", "holding", and "manufacturing/processing".

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“Facility” is defined at § 1.227(c)(2), and essentially means an establishment or structure which “holds” or “manufactures/processes” imported food articles. The definition of “facility” essentially poses little problem; however, it is the definition of “holds” or “holding”, and “manufacturing/processing” which are of the most concern.

“Holding” is defined at § 1.227(c)(5), to mean “...storage of food. Holding facilities include, but are not limited to warehouse, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.” We believe the intent of this definition is to capture those facilities which hold large quantities of food items for extended periods of time, pending some other action such as movement to a subsequent facility for processing. The essence of the definition is that products are deliberately held under physical control, i.e. restrained from movement. Conversely, transportation of food items calls for deliberate movement of those same items, under specific arrangements as defined in a bill of lading covering the movement, which bill of lading would delineate the shipper, the consignee, the date of movement, details of the shipment, liability for freight charges, and many other elements of transportation. Express transportation includes all those same items, as well as time definite service, with integrated custodial control by the express transportation provider. Therefore, the conclusion is that “holding”, as defined in this proposal, excludes transportation companies providing transportation services for movement of a shipment from a shipper to a consignee under a specific set of instructions, whether bill of lading, air waybill, or similar document.

“Manufacturing/processing” is defined at § 1.227 (c)(6), as “...making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.” Summarized in simpler language, these are food manufacturing processes the result of which is a food article used for consumption or for subsequent use in an additional process the end result of which would be a finished food article. These processes are distinct from both “holding” as defined in this proposal, and from transportation as previously discussed. A company providing transportation services for a shipment of food articles would not be engaged in any of these processes, and thus would be outside the scope of this definition.

Therefore, we conclude that transportation providers would not be required to register as a “holding” facility or as a “manufacturing/processing” facility under this proposal. Transportation providers, whether air, ocean, truck, or rail, are engaged in the movement of goods from a shipper to a consignee, which service is distinct from holding or processing. Certain transportation providers, including FedEx Express, provide additional services such as Customs clearance; however, the declaration of an import shipment to U.S. Customs and other Federal

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regulatory agencies in no way could be construed as a requirement to register as a “facility” as defined in this proposal.

For clarification, we propose the following revision to this proposal: Add an additional sentence to the definition of “holding” in § 1.227(c)(5) as follows: “The temporary staging in a carrier’s facility of a shipment in transit from a shipper to a consignee which is incidental to the transportation is not “holding” or “storage” for purposes of this definition.”

There is another section of the proposal we believe should be revised, namely § 1.227(c)(9), which defines “Port of Entry”. The proposed definition states “Port of entry means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e. the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.” This definition is at conflict with the definition by U.S. Customs, and therefore potentially troublesome. A simple difference in definition of terms between two regulatory agencies lays the groundwork for confusion and conflict regarding where and when proper declaration is required, especially where the declaration for both agencies is made by a common data set, i.e. the ABI and OASIS data transmission.

“Port of Entry” should be defined consistently with the definition currently in the Customs regulations, that being “...the port at which Customs entry is made for the shipment of imported food for consumption in the United States. This port may be different than the Port of Arrival, which is defined as the first port at which the carrier transporting the merchandise arrives.” (19 CFR 101.1). Note that Customs goes so far as to distinguish between Port of Arrival and Port of Entry, and to include a definition of Port of Arrival. These definitions would work very well for the FDA. This distinction has particular relevance for carriers who transport import shipments under Customs bond from the Port of Arrival to a different Port of Entry, where entry is made for consumption into the United States. The proposal as written would eliminate movement of imported food from “foreign facilities” from port of arrival to a different port of entry, when the foreign facility has not properly registered. This would require all carriers transporting such shipments to first determine if a shipment containing food articles is from a foreign facility, and if so, whether or not that foreign facility has properly registered, and if not, make special arrangements to discharge and hold that shipment at first port of arrival, even when the carrier’s normal regulatory processes and controls would call for such imported shipments to be sent to a subsequent port of entry. This may in fact result in carriers refusing to handle food import, which may in turn help improve the safety and security of the United States food supply chain, although not in the manner which the FDA intends. We recommend that the FDA revise the definitions of “Port of Entry” to be consistent with the definition present in the Customs regulations. We also recommend that the FDA add the term “Port of Arrival” to the definitions in § 1.227, which would be also be defined consistently with the current Customs regulations.

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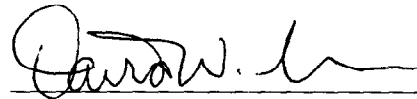
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Express carriers operate today in a manner that entails holding a shipment in their control until all regulatory agencies have released it; this means no shipment of food articles would leave an express carrier's custody until properly declared to and released by the FDA. This more properly serves the intent of the proposal, i.e. to improve the safety and security of the United States food supply, in that a food importer would be required to register as a defined "facility", and such registration will provide FDA with an improved ability to track and trace a shipment for recall, sampling, etc, as needed.

In summary, it is our understanding from the proposal as written that transportation providers would be exempt from registration requirements, and that such exemption could be more clearly stated through the revisions as suggested. We appreciate the opportunity to comment on this proposal and look forward to your response. We would also welcome the opportunity to meet with your office, either on behalf of Fedex or as the industry association (Air Courier Conference of America), should you have any questions or comments as to the foregoing.

Sincerely,

FEDERAL EXPRESS CORPORATION

A handwritten signature in dark ink, appearing to read "David W. Spence", is written over a horizontal line.

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